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January 16, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of J. Huston, P. Wils, Q. Zhu, O. Laurent, W. Marasco, & D. Scherman
Application No. 09/888,721 — Group No. 1632
Filed June 25, 2001 — Examiner C. Yaen
Bioengineered Vehicles for Targeted Nucleic Acid Delivery

(Atty. Docket No. P 23,611-A USA)

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on Friday, January 16, 2004.

Gene J. Yao

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Under separate cover, also on January 16, 2004, we filed a Request for Reconsideration in response to the Examiner's December 16, 2003 Requirement for Restriction. That copy of the Request had some clerical errors which we discovered

after the Request was mailed.

Enclosed herewith is a corrected copy of the Request for Reconsideration. Accordingly, please place this copy in the file. We request respectfully that the Examiner use the attached corrected copy when considering our Request.

Respectfully submitted,

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CORRECTED COPY

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Gene J. Yao

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REQUEST FOR RECONSIDERATION
UNDER 37 CFR §1.143 OF THE EXAMINER'S
REQUIREMENT FOR RESTRICTION, DATED DECEMBER 16, 2003

Sir:

In response to the Examiner's Requirement for Restriction of December 16, 2003, applicants elect provisionally, with traverse, the Group II claims (Claims 1 to

8, 10, 14, 16 to 29, and 52), drawn to a gene-delivery compound comprising a single-chain binding polypeptide, a nucleic acid binding moiety, and, optionally, an additional effector segment that facilitates endosomal escape or avoidance.

Applicants traverse, however, the Examiner's Requirement. It is submitted respectfully that the Examiner's Requirement is deficient because 35 U.S.C. §121 requires that the subject matter of the claim groups be independent from each other, as well as distinct. Clearly, the inventions which are defined in the various groups of claims are not independent in that there exists a disclosed relationship amongst them.

In the first instance, the claims of Groups I to IV all define a gene delivery compound comprising a single chain binding polypeptide and a nucleic acid binding moiety and Claims 1 to 8, 16 to 26, and 52 are generic to these groups. Accordingly, the claims of Groups I to IV are not independent of each other. Similarly, the claims of Groups V to VIII all define a gene delivery compound comprising a single chain binding polypeptide and a lipid-associating moiety and Claims 30 to 41 and 49 to 51 are generic to these groups. Accordingly, it is abundantly clear that the claims of Groups V to VIII are not independent of each other.

Applicants submit respectfully also that the Examiner's Requirement is based on a misunderstanding of applicants' invention. Claims 1 to 8, 16 to 26, and 52 are generic to Groups I to IV and Claims 30 to 41 and 49 to 51 are generic to Groups V to VIII. The only claims which Groups I to IV do not have in common are Claims 9 to 15 and the only claims which Groups V to VIII do not have in common are Claims 42 to 48. These claims define embodiments of the invention in which the claimed compound includes an additional effector segment, which is an optional constituent of

the claimed generic compound. This additional effector segment, be it one which is capable of associating with a nucleic acid, one which facilitates endosomal escape, one which facilitates non-endosomal transport, or one which facilitates entry into the nucleus, is an optional constituent of the generically claimed compound. Not all embodiments of the invention contain this additional effector segment. Indeed, Examples 5 to 11 and Figures 15 and 17 to 26 describe compounds of the present invention which do not contain the subject additional effector segment. Further, Claims 27 to 29, which the Examiner included in each of Groups I to IV, define conjugates which do not contain this optional additional effector segment.

Moreover, the Examiner's position is inconsistent with the position he took in framing the species for his election of species requirement. Therein, he defined the various species in part by conjugates which do not contain the optional additional effector segment. None of the species, as defined by him in the election of species requirement, contains the optional additional effector segment.

In addition, the claims of Groups I to IV and Groups V to VIII are not independent of each other because they all define a compound comprising a single-chain binding polypeptide linked to a moiety which allows for the polypeptide to be associated with a nucleic acid to be delivered in gene therapy. The moiety may be either associated directly with the nucleic acid, in which case it would be the nucleic acid-binding moiety of the claims of Groups I to IV, or it may be associated with a lipid-containing structure which in turn is associated with the nucleic acid, in which case it would be the lipid-associating moiety of the claims of Groups V to VIII. Accordingly, the nucleic acid-binding moiety of the claims of Groups I to IV and the lipid-associating moiety of the claims of Groups V to VIII are related to each other.

For the reasons above, the embodiments of the invention, as defined by the claims of the various claim groups, are not independent of each other. The Examiner has recognized apparently that the claim groups do not define independent inventions because he has not characterized them as being independent. Moreover, the Examiner has not explained why he considers the claims to be directed to independent inventions. Consequently, the Examiner has issued a Requirement that is deficient because there is no explanation of why the various claims groups are considered to define independent subject matter.

It should be noted also that, as Claims 1 to 8, 16 to 26, and 52 are generic to the claims of Groups I to IV, the claims of these groups are not patentably distinct over each other. A similar situation exists wherein Claims 30 to 41 and 49 to 51 are generic to the claims of Groups V to VIII. Accordingly, the Examiner has not established that the claims are "distinct" under the definition of that term as summarized in the MPEP at §802.1.

Given the above, the Examiner has failed to establish that the above claim groups are independent and distinct from each other, as required by 35 U.S.C. §121. Accordingly, the Examiner's Requirement for Restriction should be withdrawn.

In his Requirement, the Examiner noted that, if the claims of Group I are elected for further prosecution, applicants must elect a species of the compound defined therein to which the claims shall be restricted if no generic claim is held to be allowable. According to the Examiner, the species are defined by the type of marker to be bound by the compound, the nucleic acid binding moiety, the therapeutic gene to be bound, and the conjugate formed.

With respect to the conjugate formed, the Examiner has indicated that the conjugates defined by the claims are: C6ML3-9 sFv'-H1; C6ML3-9 sFv'-P1; and C6ML3-9 sFv'-SP. Applicants note, however, that it is possible also for conjugates of the present invention to include additional effector and/or spacer sequences such as those defined by the claims. However, conjugates of this type are not provided for by the Examiner's definition of the conjugates. Accordingly, the election with respect to the conjugates should be between the following: C6ML3-9 sFv'-H1 or its derivatives; C6ML3-9 sFv'-P1 or its derivatives; and C6ML3-9 sFv'-SP or its derivatives. Applicants will proceed, therefore, with the election with the above-revised definition for the species.

Applicants elect, with traverse, the species of applicants' invention in which the marker to be bound is erbB2, the nucleic acid binding moiety is salmon protamine, the conjugate is C6ML3-9sFv'-SP or its derivatives, and the therapeutic gene is a tumor suppressor gene. Claims 1 to 22, 26, 29, and 52 read on this species.

Although applicants have elected a species, it is submitted respectfully that the different types of markers to be bound by the compound serve the same purpose, that being a site for binding the compound, and operate by the same means, that being their affinity for the single chain polypeptide. The different types of nucleic acid binding moieties serve the same purpose, that of binding a nucleic acid, and operate by the same means, that being their affinity for the nucleic acid. The different types of conjugate serve the same purpose, that of binding both a nucleic acid and a marker on a cell, and operate by the same means, that being their affinity for both the nucleic acid and a marker. It appears, therefore, that a proper search of

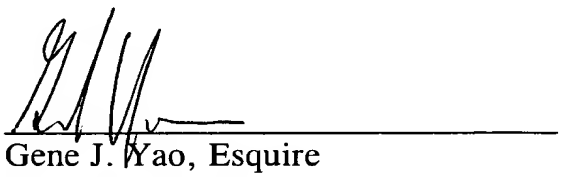
the subject matter of one species of applicants' invention cannot be done except that a search is conducted for the subject matter of all species. This is so because the subject matter of the species is so interrelated.

In addition to the above, applicants assert respectfully that the Examiner's characterization of the species for election is improper because the species ought not be defined by the type of therapeutic gene bound. Applicants would like to emphasize that, unlike the case with the above marker to be bound, the interaction between the nucleic acid binding moiety and the therapeutic gene may be non-specific. For example, the nucleic acid binding moiety may be cationic and, therefore, bind non-specifically DNA which is anionic. Accordingly, it is the case that it is possible to use the same gene-delivery compound regardless of what therapeutic gene is to be bound and, therefore, distinct species of the invention are not defined by what therapeutic gene is bound by the compound. This being the case, applicants assert that the use of the therapeutic gene to be bound in defining the species of applicants' invention is improper.

For the reasons expressed above, applicants traverse respectfully the Examiner's election of species requirement.

In view of the foregoing, an early and favorable Action is requested.

Respectfully submitted,



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